IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

AMGEN INC. and AMGEN MANUFACTURING LIMITED, Plaintiffs, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., MYLAN GMBH and MYLAN N.V., Defendants.	)	Civil Action No. _____ ***Electronically Filed*** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. (collectively, "Defendants") hereby allege as follows:

THE PARTIES

1. Amgen Inc. ("Amgen") is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. Founded in 1980, Amgen is a pioneer in the development of biological human therapeutics. Today, Amgen is the largest biotechnology company in the world, fueled in part by the success of NEULASTA® (pegfilgrastim).

2. Amgen Manufacturing Limited ("AML") is a corporation existing under the laws of the Territory of Bermuda with its principal place of business at Road 31 km 24.6, Juncos,

Puerto Rico 00777. AML manufactures and sells biologic medicines for treating particular diseases in humans. AML is a wholly owned subsidiary of Amgen.

3. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business in Canonsburg, Pennsylvania at 1000 Mylan Boulevard Canonsburg, Pennsylvania 15317. Upon information and belief, acting in concert with the other Defendants, Mylan Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

4. Upon information and belief, Mylan Inc. is a United States agent for Mylan GmbH and Mylan N.V. for purposes including, but not limited to, corresponding with the Food and Drug Administration ("FDA").

5. Upon information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, with its principal place of business in Morgantown, West Virginia at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, acting in concert with the other Defendants, Mylan Pharmaceuticals Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

6. Upon information and belief, Mylan Pharmaceuticals Inc. is a United States agent for Mylan GmbH and Mylan N.V. for purposes including, but not limited to, corresponding with FDA.

7. Upon information and belief, Mylan GmbH is a corporation existing under the laws of the Republic of Switzerland with its principal place of business at Thurgauerstrasse 40

Zurich, 8050 Switzerland. Upon information and belief, acting in concert with each of the other Defendants, Mylan GmbH is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

8. Upon information and belief, Mylan N.V. is a corporation existing under the laws of the Republic of Netherlands with its global headquarters and principal offices located in Canonsburg, Pennsylvania, and its principal executive offices located Hatfield, Hertfordshire, England. Upon information and belief, acting in concert with each of the other Defendants, Mylan N.V. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

9. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan GmbH are wholly owned subsidiaries of Mylan N.V.

10. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc.

11. Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in the Commonwealth of Pennsylvania and throughout the United States.

NATURE OF THE ACTION

12. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act of 2009 ("the

BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (amending, inter alia, 35 U.S.C. § 271 and 42 U.S.C. § 262).

13. The asserted patents are U.S. Patent No. 8,273,707 ("the '707 Patent") and U.S. Patent No. 9,643,997 ("the '997 Patent"). Amgen is the owner of all rights, title, and interest in the '707 and '997 Patents. The '707 and '997 Patents claim methods of purifying proteins used in the manufacture of a biological product.

14. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). The abbreviated pathway (also known as "the subsection (k) pathway") allows a biosimilar applicant (here, Mylan GmbH, acting in concert with the other Defendants) to rely on the prior licensure and approval status of the innovative biological product (here, NEULASTA®) that the biosimilar purports to copy. Amgen is the sponsor of the reference product ("reference product sponsor" or "RPS"), NEULASTA®, which is approved by FDA to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. Under the subsection (k) pathway, the biosimilar applicant may rely on its reference product's data rather than demonstrating that a biological product is safe, pure, and potent, as Amgen was required to do to obtain FDA licensure of its reference product under 42 U.S.C. § 262(a).

15. To avoid burdening the courts and parties with unnecessary disputes, the BPCIA also creates an intricate and carefully orchestrated set of procedures for the biosimilar applicant and the RPS to engage in a series of information exchanges and good-faith negotiations between parties prior to the filing of a patent infringement lawsuit. These exchanges are set forth in 42 U.S.C. § 262(*l*)(2)-(*l*)(5) and culminate in an "immediate patent infringement action" pursuant to 42 U.S.C. § 262(*l*)(6).

16. Seeking the benefits of the subsection (k) pathway, Mylan GmbH, acting in concert with the other Defendants, submitted Defendants' abbreviated Biologics License Application No. 761075 (the "Mylan aBLA") to FDA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k), requesting that its biological product ("the Mylan Pegfilgrastim Product") be licensed by relying on Amgen's demonstration that NEULASTA® (pegfilgrastim) is "safe, pure, and potent."

17. Upon information and belief Mylan GmbH, acting in concert with the other Defendants, submitted the Mylan aBLA to FDA prior to February 2017, and thus before the expirations of the '707 Patent and the '997 Patent.

18. Upon information and belief, Defendants received FDA acceptance of the Mylan aBLA for review on or about February 7, 2017.

19. In March 2017, the parties began exchanging information as required by the BPCIA.

20. The '707 Patent was included on Amgen's May 1, 2017 disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pursuant to 42 U.S.C. § 262(*l*)(7), the '997 Patent was included on Amgen's June 7, 2017 supplement to its 42 U.S.C. § 262(*l*)(3)(A) list.

21. Under 35 U.S.C. § 271(e)(2)(C)(i), it is an act of infringement to submit an application seeking approval of a biological product with respect to patents identified in the lists of patents described in 42 U.S.C. § 262(*l*)(3) if the purpose of such submission is to obtain approval to engage in the commercial manufacture, use, or sale of a biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. *See Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1672 (2017).

22. Here, Defendants committed an act of infringement with respect to each of the ’707 and ’997 Patents under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Mylan GmbH to submit the Mylan aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product.

23. If FDA approves the Mylan aBLA and Defendants import the Mylan Pegfilgrastim Product into the United States, or offer to sell, sell, or use the Mylan Pegfilgrastim Product within the United States, Defendants will also infringe one or more claims of the ’707 and ’997 Patents under 35 U.S.C. § 271(g).

JURISDICTION AND VENUE

24. This action arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code.

25. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

26. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

27. Upon information and belief, Mylan Pharmaceuticals Inc. has a regular and established place of business in Pennsylvania. Upon information and belief, Mylan Pharmaceuticals Inc. is licensed to do business in Pennsylvania as a foreign business corporation.

28. This Court has personal jurisdiction over each of the Defendants for the reasons set forth below.

A. Mylan Inc.

29. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

30. This Court has personal jurisdiction over Mylan Inc. by virtue of, among other things, Mylan Inc. being a Pennsylvania corporation; having its principal place of business in Canonsburg, Pennsylvania; having availed itself of the rights and benefits of Pennsylvania law; and having engaged in substantial and continuing contacts with Pennsylvania.

B. Mylan Pharmaceuticals Inc.

31. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

32. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc., which exercises considerable control over Mylan Pharmaceuticals Inc.

33. Upon information and belief, Mylan Pharmaceuticals Inc. develops, manufactures, seeks regulatory approval for, markets, distributes, and sells biopharmaceuticals for sale and use throughout the United States, including in Pennsylvania and this federal judicial District.

34. This Court has personal specific jurisdiction over Mylan Pharmaceuticals Inc. because, upon information and belief, following any FDA approval of the Mylan Pegfilgrastim Product, Mylan Pharmaceuticals Inc. will sell the Mylan Pegfilgrastim Product that is the subject of the patent infringement claims in this action in Pennsylvania and throughout the United States.

35. This Court has personal general jurisdiction over Mylan Pharmaceuticals Inc. by virtue of, inter alia, its having conducted business in this District, having availed itself of the rights and benefits of Pennsylvania law, and having engaged in substantial and continuing contacts with Pennsylvania. Upon information and belief, Mylan Pharmaceuticals Inc. has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in Pennsylvania and this District. In addition, Mylan Pharmaceuticals Inc. has availed itself of this Court by asserting claims in this District, *see, e.g.*, *Mylan Inc., Mylan Pharmaceuticals, Inc. v. Boehringer Ingelheim International GmbH, et al.*, Case No. 09-00990-GLL (W.D. Pa. complaint filed July 7, 2009), and by asserting counterclaims against plaintiffs in this judicial District and by consenting to this Court as a patent infringement defendant, *see, e.g., Takeda Pharmaceutical Company Limited, et al. v. Mylan Inc., Mylan Pharmaceuticals Inc.*, Case No. 12-00026-AJS (W.D. Pa. answer and counterclaims filed Jan. 23, 2012).

C. Mylan GmbH

36. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

37. Upon information and belief, Mylan GmbH collaborates with Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan N.V. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in Pennsylvania and in the United States.

38. Upon information and belief, Mylan GmbH operates as a subsidiary of Mylan N.V., which exercises considerable control over Mylan GmbH.

39. This Court has personal specific jurisdiction over Mylan GmbH because, upon information and belief, Mylan GmbH submitted the Mylan aBLA seeking approval from FDA to market and sell the Mylan Pegfilgrastim Product in the Commonwealth of Pennsylvania and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement.

40. Further, upon information and belief, Mylan GmbH has or will directly or indirectly manufacture, import into the United States, and/or sell the Mylan Pegfilgrastim Product that is the subject of the infringement claim in this action in Pennsylvania and throughout the United States.

41. Additionally, upon information and belief, Mylan GmbH exercises considerable control over Mylan Inc. and Mylan Pharmaceuticals Inc. with respect to biosimilar products, and approves significant decisions of Mylan Inc. and Mylan Pharmaceuticals Inc. such as allowing Mylan Inc. and Mylan Pharmaceuticals Inc. to act as United States agents in connection with preparing and submitting the Mylan aBLA.

42. Additionally, and in the alternative, Plaintiffs allege that to the extent Mylan GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the Commonwealth of Pennsylvania, Mylan GmbH likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

D. Mylan N.V.

43. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

44. Upon information and belief, Mylan N.V. collaborates with Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan GmbH to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in Pennsylvania and in the United States.

45. Upon information and belief, Mylan GmbH operates as a subsidiary of Mylan N.V., which exercises considerable control over Mylan GmbH.

46. Mylan N.V. has issued at least one press release regarding the Mylan Pegfilgrastim Product and its regulatory status. *See* Press Release, Mylan N.V., "U.S. FDA Accepts Biologics License Application (BLA) for Mylan and Biocon's Proposed Biosimilar Pegfilgrastim for Review" (Feb. 16, 2017), http://newsroom.mylan.com/2017-02-16-U-S-FDA-Accepts-Biologics-License-Application-BLA-for-Mylan-and-Biocons-Proposed-Biosimilar-Pegfilgrastim-for-Review, attached hereto as Exhibit 1.

47. According to the Defendants' website (page attached hereto as Exhibit 2) "[t]he Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania."

48. This Court has personal jurisdiction over Mylan N.V. by virtue of, among other things, Mylan N.V. having its global headquarters and principal offices in Canonsburg, Pennsylvania; having availed itself of the rights and benefits of Pennsylvania law; and having engaged in substantial and continuing contacts with Pennsylvania.

49. Additionally, this Court has personal specific jurisdiction over Mylan N.V. because, upon information and belief, the acts of Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan GmbH complained of herein were done, in part, for the benefit of Mylan N.V. Further,

upon information and belief, Mylan N.V. has or will directly or indirectly manufacture, import into the United States, and/or sell the Mylan Pegfilgrastim Product that is the subject of the infringement claim in this action in Pennsylvania and throughout the United States.

50. Additionally, upon information and belief, Mylan N.V. exercises considerable control over Mylan Inc. and Mylan Pharmaceuticals Inc. with respect to biosimilar products, and approves significant decisions of Mylan Inc. and Mylan Pharmaceuticals Inc. such as allowing Mylan Inc. and Mylan Pharmaceuticals Inc. to act as United States agents in connection with preparing and submitting the Mylan aBLA.

51. Additionally, and in the alternative, Plaintiffs allege that to the extent Mylan N.V. is not subject to the jurisdiction of the courts of general jurisdiction of the Commonwealth of Pennsylvania, Mylan N.V. likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

BACKGROUND

A. Amgen's Innovative Biological Product: NEULASTA® (pegfilgrastim)

52. Amgen is one of the world's leading biopharmaceutical companies and is dedicated to using discoveries in human biology to invent, develop, manufacture, and sell new therapeutic products for the benefit of patients suffering from serious illnesses. Toward that end, Amgen has invested billions of dollars into its research and development efforts.

53. In 2002, Amgen introduced NEULASTA® (pegfilgrastim), an innovative biologic medicine which has benefited millions of cancer patients as a treatment of side effects of certain forms of cancer therapy. Amgen conducted extensive clinical trials and submitted the results of those trials to FDA in order to prove that NEULASTA® is safe, pure, and potent.

54. The active ingredient in Amgen's innovative NEULASTA® product is pegfilgrastim, a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor ("G-CSF") conjugated to a 20 kD monomethoxypolyethylene glycol (m-PEG) at the N-terminus of G-CSF.

55. NEULASTA® is indicated to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. By binding to specific receptors on the surface of certain types of cells, NEULASTA® stimulates the production of a type of white blood cells known as neutrophils. Neutrophils are the most abundant type of white blood cells and form a vital part of the human immune system. A deficiency in neutrophils is known as neutropenia, a condition which makes the individual highly susceptible to infection. Neutropenia can result from a number of causes; it is a common side effect of chemotherapeutic drugs used to treat certain forms of cancer. NEULASTA® counteracts neutropenia.

56. NEULASTA® represented a major advance in cancer treatment by protecting chemotherapy patients from the harmful effects of neutropenia and by facilitating more effective chemotherapy regimens.

57. Prior to 2010, any other company wishing to sell its own version of NEULASTA® would have had to undertake the same extensive effort to conduct clinical trials to prove to FDA that its proposed version was also safe, pure, and potent.

58. Developing a new therapeutic product from scratch is extremely expensive: studies estimate the cost of obtaining FDA approval of a new biologic product at more than $2.5 billion. *See* DiMasi J.A. *et al.*, Innovation in the pharmaceutical industry: New estimates of R&D costs, 47 J. Health Econ. 20, 25-26 (2016), attached hereto as Exhibit 3.

B. Defendants Seek Approval To Market a Proposed Biosimilar Version of NEULASTA® (pegfilgrastim) by Taking Advantage of the Abbreviated Subsection (k) Pathway of the BPCIA

59. Upon information and belief, Mylan GmbH, acting in concert with the other Defendants, submitted the Mylan aBLA with FDA pursuant to Section 351(k) of the Public Health Service Act in order to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States the Mylan Pegfilgrastim Product, a biosimilar version of Plaintiffs' NEULASTA® (pegfilgrastim) product.

60. Upon information and belief, the Mylan aBLA references and relies on the approval and licensure of Plaintiffs' NEULASTA® (pegfilgrastim) product in support of Defendants' request for FDA approval.

61. Upon information and belief, the Mylan Pegfilgrastim Product is designed to copy and compete with Plaintiffs' NEULASTA® (pegfilgrastim).

62. Upon information and belief, Defendants did not seek to independently demonstrate to FDA that their biological product is "safe, pure, and potent" pursuant to 42 U.S.C. § 262(a), as Amgen did in its BLA for its innovative biological product NEULASTA® (pegfilgrastim). Rather, upon information and belief, Defendants requested that FDA evaluate the suitability of their biological product for licensure, expressly electing and seeking reliance on Amgen's FDA license for NEULASTA® (pegfilgrastim). Accordingly, Defendants submitted to FDA publicly available information regarding FDA's previous licensure determination that NEULASTA® (pegfilgrastim) is "safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I).

63. Defendants are piggybacking on the fruits of Plaintiffs' trailblazing efforts. Defendants have publicly announced that they submitted the Mylan aBLA under the subsection (k) pathway to obtain approval to commercially manufacture, use, offer to sell, and sell, and

import into the United States the Mylan Pegfilgrastim Product that they assert is a biosimilar version of Plaintiffs' NEULASTA®. *See* Press Release, Mylan N.V., "U.S. FDA Accepts Biologics License Application (BLA) for Mylan and Biocon's Proposed Biosimilar Pegfilgrastim for Review" (Feb. 16, 2017), http://newsroom.mylan.com/2017-02-16-U-S-FDA-Accepts-Biologics-License-Application-BLA-for-Mylan-and-Biocons-Proposed-Biosimilar-Pegfilgrastim-for-Review, attached hereto as Exhibit 1.

C. Information Exchange Under 42 U.S.C. § 262(*l*)

64. In March 2017, the exchange of information between Amgen and Mylan GbmH, as required by the BPCIA, began.

65. On March 2, 2017, pursuant to 42 U.S.C. § 262(*l*)(2)(A), Mylan GmbH provided Amgen's counsel with access to the Mylan aBLA.

66. Upon information and belief, the Mylan aBLA provided to Amgen was in a format different than and less complete than the format provided to FDA.

67. Upon information and belief, the Mylan aBLA was provided to FDA in Electronic Common Technical Document (eCTD) format with fully working hyperlinks and without restrictions on, inter alia, viewing, copying, and printing.

68. Mylan GmbH's failure to provide "a copy of the application submitted to the Secretary under subsection (k)" as required by 42 U.S.C. § 262(*l*)(2)(A) materially prejudiced and impeded Amgen's ability to review the Mylan aBLA. For example: Mylan GmbH uploaded the Mylan aBLA to a virtual data room (the "ShareVault data room") and provided Amgen's counsel with credentials to access the documents and data on the ShareVault data room. Mylan GmbH configured the ShareVault data room to prohibit Amgen from, inter alia, saving, copying, annotating, or printing any documents or data on the ShareVault data room. The ShareVault data room is also slow and cumbersome, and lacks fully working hyperlinks. In

addition, Amgen was and, in some cases, continues to be unable to view many of the documents and data on the ShareVault data room, including many of the xml, xsl, sas, xpt, jpeg, and txt files. Additionally, the ShareVault data room suffered periodic technological failures, preventing Amgen from accessing or viewing the documents and data on the ShareVault data room.

69. Mylan GmbH also failed to provide "other information that describes the process or processes used to manufacture the biological product that is the subject of" the Mylan aBLA, pursuant to 42 U.S.C. § 262(*l*)(2)(A). In April and May 2017, Amgen requested certain specific categories of documents that it believes exist and describe the Defendants' process for manufacturing the Mylan Pegfilgrastim Product. Mylan GmbH undertook to consider Amgen's request but, to date, has failed to provide such documents.

70. On May 1, 2017, Amgen provided Mylan GmbH with Amgen's list of patents under 42 U.S.C. § 262(*l*)(3)(A). That list included the '707 Patent and U.S. Patent No. 8,940,878 ("the '878 Patent"). On June 5, 2017, Mylan GmbH provided its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases of Mylan GmbH's opinions that the '707 and '878 Patents are invalid, are unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA.

71. On June 7, 2017, pursuant to 42 U.S.C. § 262(*l*)(7) Amgen supplemented its 42 U.S.C. § 262(*l*)(3)(A) list to include the '997 Patent. On June 9, 2017, Mylan GmbH provided a detailed statement pursuant to 42 U.S.C. § 262(*l*)(7) describing the factual and legal bases of Mylan GmbH's opinions that the '997 Patent is invalid, is unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA.

72. On August 4, 2017, Amgen provided its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) describing the factual and legal bases of Amgen's opinion that certain claims of the '707 and '878 Patents will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA, and Amgen's responses to the invalidity and unenforceability assertions against the '707 and '878 Patents in Mylan GmbH's statement under 42 U.S.C. § 262(*l*)(3)(B).

73. On August 8, 2017, Amgen provided Mylan GmbH with the factual and legal bases of Amgen's opinion that certain claims of the '997 will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA and responses to the invalidity and unenforceability assertions against the '997 Patent in Mylan GmbH's June 9, 2017 statement.

74. Amgen and Mylan GmbH then negotiated under 42 U.S.C. § 262(*l*)(4) as to "which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6)." Failing to reach agreement, Amgen and Mylan GmbH exchanged lists pursuant to the procedures of 42 U.S.C. § 262(*l*)(5) on August 25, 2017. Amgen asserted that there should be an immediate patent infringement action on the '707 and '997 Patents, but not on the '878 Patent.

75. Accordingly, Plaintiffs now file this immediate patent infringement action against Defendants pursuant to 42 U.S.C. § 262(*l*)(6)(B) on the '707 and '997 Patents. This action follows "not later than 30 days after the exchange of lists under paragraph (5)(B)."

THE PATENTS-IN-SUIT: U.S. PATENT NOS. 8,273,707 AND 9,643,997

76. Amgen is the owner of all rights, title, and interest in the '707 Patent.

77. AML is the exclusive licensee under the '707 Patent.

78. The ’707 Patent, titled “Process For Purifying Proteins,” was duly and legally issued on September 25, 2012 by the U.S. Patent and Trademark Office. A true and correct copy of the ’707 Patent is attached to this Complaint as Exhibit 4.

79. The ’707 Patent is directed to a process for purifying proteins.

80. Amgen is the owner of all rights, title, and interest in the ’997 Patent.

81. AML is the exclusive licensee under the ’997 Patent.

82. The ’997 Patent, titled “Capture Purification Processes for Proteins Expressed in a Non-Mammalian System,” was duly and legally issued on May 9, 2017 by the U.S. Patent and Trademark Office. A true and correct copy of the ’997 Patent is attached to this Complaint as Exhibit 5.

83. The ’997 Patent is directed to a process for purifying proteins.

CAUSES OF ACTION

FIRST COUNT:
INFRINGEMENT OF THE ’707 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(i)

84. Amgen incorporates by reference paragraphs 1-83 as if fully set forth herein.

85. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product, a proposed biosimilar version of Amgen’s NEULASTA® (pegfilgrastim) product.

86. Defendants committed an act of infringement with respect to the ’707 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Mylan GmbH to submit the Mylan aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product.

87. Upon information and belief, Defendants intend to manufacture, use, sell, and/or offer for sale within the United States, and/or import into the United States, the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

88. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan Pegfilgrastim Product will infringe, literally or under the doctrine of equivalents, one or more claims of the '707 Patent.

89. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Amgen has provided Defendants with a detailed statement describing with respect to the '707 Patent, on a claim by claim basis, the factual and legal bases of Amgen's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA. Amgen's detailed statement includes, refers to, and relies on confidential information that Mylan GmbH provided to Amgen pursuant to 42 U.S.C. § 262(*l*)(2). Amgen does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1), Amgen is not permitted to include confidential information provided by Mylan GmbH "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

90. Representative claim 1 of the '707 Patent recites:

> A process for purifying a protein on a hydrophobic interaction chromatography column such that the dynamic capacity of the column is increased for the protein comprising
>
> > mixing a preparation containing the protein with a combination of a first salt and a second salt,
> >
> > loading the mixture onto a hydrophobic interaction chromatography column, and
> >
> > eluting the protein,

> wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and wherein the concentration of each of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0.

'707 Patent at col. 15:8-18. Upon information and belief, the process by which Defendants manufacture the Mylan Pegfilgrastim Product satisfies each limitation of at least claims 1, 2, 6, 8, 10, and 11, literally or equivalently. With respect to the requirement that the protein is purified on a hydrophobic interaction chromatography column, Defendants practice a process for purifying a protein on a hydrophobic interaction chromatography column as defined in the '707 patent. With respect to the use of a combination of a first salt and a second salt, in the Defendants' process, a preparation containing protein becomes mixed with a first salt and a second salt as recited in the claim. With respect to the salt concentration, the concentration of the salts in the Defendants' process falls within the claimed range and/or is equivalent to a concentration within the claimed range. In the Defendants' process, after the protein is loaded onto the hydrophobic interaction chromatography column in the presence of the combination of salts, the protein is eluted.

91. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '707 Patent. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from any further infringement under 35 U.S.C. § 271(e)(4)(B).

92. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '707 Patent will cause injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

SECOND COUNT:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '707 PATENT UNDER 35 U.S.C. § 271(g)

93. Plaintiffs incorporate by reference paragraphs 1-92 as if fully set forth herein.

94. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Mylan Pegfilgrastim Product, a biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

95. Upon information and belief, FDA may act upon the Mylan aBLA as soon as October 2017. FDA has stated publicly that the agency's goal is to act upon 90% of aBLA applications within 10 months of the 60-day-filing-review period that begins on the date of FDA receipt of the original aBLA submission. *See* Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, *available at* https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf.

96. Upon information and belief, Defendants intend to, and will upon FDA licensure of the Mylan aBLA, import into the United States or offer to sell, sell, or use within the United States the Mylan Pegfilgrastim Product, which will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(g).

97. An actual controversy has arisen and now exists between the parties concerning whether the Mylan Pegfilgrastim Product has or will infringe one or more claims of the '707 Patent.

98. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '707 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

99. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '707 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

100. Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '707 Patent will cause injury to Plaintiffs, entitling them to damages under 35 U.S.C. § 284.

THIRD COUNT:
INFRINGEMENT OF THE '997 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(i)

101. Amgen incorporates by reference paragraphs 1-100 as if fully set forth herein.

102. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product, a proposed biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

103. Defendants committed an act of infringement with respect to the '997 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Mylan GmbH to submit the Mylan aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product.

104. Upon information and belief, Defendants intend to manufacture, use, sell, and/or offer for sale within the United States, and/or import into the United States, the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

105. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan

Pegfilgrastim Product will infringe, literally or under the doctrine of equivalents, one or more claims of the '997 Patent.

106. Amgen has provided Defendants with a statement describing with respect to the '997 Patent the factual and legal bases of Amgen's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA. Amgen's statement includes, refers to, and relies on confidential information that Mylan GmbH provided to Amgen pursuant to 42 U.S.C. § 262(*l*)(2). Amgen does not repeat its statement here because under 42 U.S.C. § 262(*l*)(1), Amgen is not permitted to include confidential information provided by Mylan GmbH "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

107. Representative claim 9 of the '997 Patent recites:

> A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
>
> (a) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) a reductant; and
>
> (iii) a surfactant;
>
> (b) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) an aggregation suppressor;
>
> (iii) a protein stabilizer; and
>
> (iv) a redox component;
>
> (c) applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;
>
> (d) washing the separation matrix; and
>
> (e) eluting the protein from the separation matrix.

'997 Patent at col. 22:36-55. Upon information and belief, the process by which Defendants manufacture the Mylan Pegfilgrastim Product satisfies each limitation of at least independent claim 9 and also certain dependent claims, literally or equivalently. With respect to the

requirement that the protein is expressed in a non-native limited solubility form in a non-mammalian expression system, Defendants practice a process for purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system. With respect to the requirement of the "solubilizing" step, in the Defendants' process, protein is solubilized in a solubilization solution comprising one or more of a denaturant, reductant, and surfactant. With respect to the requirement of the "forming" step, in the Defendants' process, a refold solution is formed comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of a denaturant, aggregation suppressor, protein stabilizer, and redox component. With respect to the requirement of the "applying" step, the Defendants' refold solution is applied to a separation matrix under conditions suitable for the protein to associate with the matrix. With respect to the requirement of the "washing" step, the Defendants' separation matrix is washed. With respect to the requirement of the "eluting" step, Defendants' protein is eluted from the separation matrix.

108. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '997 Patent. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from any further infringement under 35 U.S.C. § 271(e)(4)(B).

109. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '997 Patent will cause injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

FOURTH COUNT:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '997 PATENT UNDER 35 U.S.C. § 271(g)

110. Plaintiffs incorporate by reference paragraphs 1-109 as if fully set forth herein.

111. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Mylan Pegfilgrastim Product, a biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

112. Upon information and belief, FDA may act upon the Mylan aBLA as soon as October 2017. FDA has stated publicly that the agency's goal is to act upon 90% of aBLA applications within 10 months of the 60-day-filing-review period that begins on the date of FDA receipt of the original aBLA submission. *See* Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, *available at* https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf.

113. Upon information and belief, Defendants intend to, and will upon FDA licensure of the Mylan aBLA, import into the United States or offer to sell, sell, or use within the United States the Mylan Pegfilgrastim Product, which will infringe one or more claims of the '997 Patent under 35 U.S.C. § 271(g).

114. An actual controversy has arisen and now exists between the parties concerning whether the Mylan Pegfilgrastim Product has or will infringe one or more claims of the '997 Patent.

115. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '997 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

116. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '997 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to

sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the ’997 Patent.

117. Defendants’ manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the ’997 Patent will cause injury to Plaintiffs, entitling them to damages under 35 U.S.C. § 284.

DEMAND FOR A JURY TRIAL

118. Plaintiffs hereby demand a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor against Defendants and grant the following relief:

A. a judgment that Defendants have infringed one or more claims of the ’707 Patent under 35 U.S.C. § 271(e)(2)(C)(i);

B. a judgment that Defendants have infringed or will infringe one or more claims of the ’707 Patent under 35 U.S.C. § 271(g);

C. a judgment that Defendants have infringed one or more claims of the ’997 Patent under 35 U.S.C. § 271(e)(2)(C)(i);

D. a judgment that Defendants have infringed or will infringe one or more claims of the ’997 Patent under 35 U.S.C. § 271(g);

E. a judgment compelling Defendants to pay to Plaintiffs damages or other monetary relief adequate to compensate for Defendants’ infringement, in accordance with 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284;

F. an order enjoining Defendants, as well as all officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates of Defendants, and all persons acting on behalf of or at the direction of, or in concert with Defendants, from infringing the ’707

Patent, or contributing to or inducing anyone to do the same, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

G. an order enjoining Defendants, as well as all officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates of Defendants, and all persons acting on behalf of or at the direction of, or in concert with Defendants, from infringing the '997 Patent, or contributing to or inducing anyone to do the same, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

H. a declaration that this is an exceptional case and awarding to Plaintiffs their attorneys' fees and costs pursuant to 35 U.S.C. § 285, and expenses; andsuch other relief as this Court may deem just and proper.

Respectfully submitted,

THE WEBB LAW FIRM

Dated: September 22, 2017

s/ *Kent E. Baldauf, Jr.*

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